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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,800	05/23/2000	David W. Cannell	05725.0572	2688
22852	7590	11/19/2003		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			EXAMINER FLOOD, MICHELE C	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/576,800	CANNELL ET AL.	
	Examiner	Art Unit	
	Michele C. Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 10, 2003 has been entered.

Specification

The disclosure is objected to because of the following informalities: On page 17, line 3, of the specification recites "Potato HS" without setting forth the meaning of the abbreviation of "HS". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks adequate written description for the claimed invention in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, describing a combination of ingredients in the making of a composition for use in a method of protecting keratinous fibers from extrinsic damage, in the absence of knowledge as to what the material consists of is not a description of that material or the method of use thereof. In the instant case, on page 21, lines 2-4 of the specification, Applicant discloses plant extracts containing 60-80% glycerol, *i.e.*, avocado extract, mistletoe extract, and wheat germ extract, obtained from Active Organics. On page 7, line 3 10 through page 10, line 8, the specification further discloses that plant extracts

that are useful in the invention, e.g., any plant extract that binds to carbohydrate moieties or sugars, plant extracts in water or glycerol containing solutions, and plant extracts containing lectins. However, other than the mere mention that the plant extracts used in the instantly claimed method were obtained from Active Organics, it is unclear from the specification the ingredients and the percentage of the ingredients comprising the plant extracts used in the making of the demonstrated combination of plant extract and sugar having the claimed therapeutic effect. Although Applicant identifies a manufacturer from which the plant extracts may be obtained, Applicant fails to disclose the characteristics of the product. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. Thus, Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The broad generic claim lacks sufficient description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by complete structure or identifying characteristics, thus the description requirement has not been satisfied, see *Eli Lilly*, 119 F. 3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1977).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 are rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. An "extract" is necessarily a product-by-process because the composition of the "extract" is only defined by the process of its preparation. Such product-by-process claims are intended to define products which are otherwise difficult to define and/or distinguish from the prior art except by the process of making. Since any given biological source contains thousands of extractable compounds, each with its own particular extraction properties, the nature of the resulting "extract" will depend on the conditions of the extraction and the solvent used. For example, at what temperature is the extraction performed; is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, or an acid or base, or is it a squeezed extract? It is well accepted in the natural products and herbal art, that extraction of a biological source with one of various distinct solvents has a profound impact on the final product with respect to the presence, amounts, and/or ratios of active ingredients obtained, and, thus, on the ability of the "extract" to provide the desired functional effect(s) claimed and/or disclosed. Since the "extract" itself is clearly essential to the instantly claimed invention, the step(s) by which the claimed "extract" is/are obtained is/are also clearly essential and, therefore, must be

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recited in the claims (i.e., as a product-by-process). Although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fath et al. (N).

Applicant claims a method of protecting keratinous fiber from extrinsic damage comprising applying to said keratinous fiber a composition comprising an effective amount of at least one plant extract chosen from wheat germ extract and willowherb extract. Applicant further claims a method of protecting keratinous fiber from extrinsic damage according to claim 1, wherein said composition further comprises at least one sugar. Applicant further claims a method of protecting keratinous fiber from extrinsic damage according to claim 2, wherein said sugar is chosen from monosaccharides,

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disaccharides and polysaccharides. Applicant further claims a method of protecting keratinous fiber from extrinsic damage according to claim 3, wherein said disaccharides are chosen from maltose, sucrose, cellobiose, trehalose and lactose. Applicant further claims a method of protecting keratinous fiber from extrinsic damage according to claim 1, wherein said composition is in the form of a liquid, oil, paste, stick, dispersion, emulsion, lotion, gel, or cream; wherein said keratinous fiber is chosen from hair, eyelashes, and eyebrows; and, wherein said at least one plant extract is present in said composition at a concentration ranging from 0.01% to 5.0% relative to the total weight of the composition. Applicant further claims a method of protecting keratinous fiber from extrinsic damage according to claim 2, wherein said at least one sugar is present in said composition at a concentration ranging from 0.001% to 3.0% relative to the total weight of the composition.

Fath teaches a hair treatment composition green tea extract (a plant extract comprising 1.31% of the total composition), wheat germ oil (a plant extract comprising 0.5% of the total composition), and sucrose (a monosaccharide comprising 1.31% of the total composition), which has the intended purpose for applying to hair. Fath further teaches that the referenced hair treatment composition comprises mono- or oligosaccharide. Fath does not expressly teach that the composition can be used in the manner instantly claimed. However, Fath does teach that the referenced composition improves wet and dry combability, luster, feel, and style retention when applied to hair. Thus, a method of protecting keratinous fiber from extrinsic damage is inherent to the use of the composition taught by Fath, given that the referenced composition comprises

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the instantly claimed ingredients of at least one plant extract of wheat germ, *i.e.*, wheat germ oil, and at least one of the instantly claimed monosaccharides, *i.e.*, sucrose, and given that Applicant readily admits on page 10 of the present application, lines 9-17, "The combability test (See Garcia, M.L., and Diaz, J., J. Soc. Cosmet. Chem. 27, 370-398 (1976)), is known in the art to correlate well to the amount of protection from exposure to extrinsic conditions that is afforded by hair by a composition."

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 7 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fath et al. (N) in view of Pineu et al. (A).

Applicant's claimed invention of Claims 1-3, 7 and 10-13 was set forth above. Applicant further claims a method of protecting keratinous fiber from extrinsic damage according to claim 3, wherein said monosaccharide are chosen from pentoses and hexoses. Applicant further claims a method of protecting keratinous fiber from extrinsic damage according to claim 4, wherein said pentoses are chosen from ribose, arabinose, xylose, lyxose, ribulose, and xylulose, and wherein said hexoses are chosen

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from allose, altrose, glucose, mannose, gulose, idose, galactose, talose, sorbose, psicose, fructose, and tagatose.

The teachings of Fath were set forth above. Fath teaches the claimed invention except for the claimed monosaccharides. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed sugars to the intended use of the composition taught by Fath to provide the claimed method because Pineau teaches that the claimed ingredients were effective in the making of therapeutic compositions having the claimed functional effect for the protection of keratinous fibers from extrinsic damage. For instance, Pineau teaches a composition comprising heterogenous polyholosides comprising 2 to 10 oses or monosaccharides. Pineau teaches the sugar containing compositions as active agents to combat extrinsic aging of the skin and hair. See Column 3, lines 43-67 to Column 4, lines 1-64. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the sugars taught by Pineau to the method of using the hair treatment composition by Fath because Pineau teaches that the polyholoside compositions of his invention have the beneficial effect of keratinous tissue, such as hair, from extrinsic damage when used in the formulation of cosmetics, pharmaceuticals, and dermatological compositions.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following

reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, the claimed invention is no more than the combining of well known methods for the application of well known ingredients which are known in the art for their beneficial effect of protecting keratinous fiber from extrinsic damage to provide an additive effect, as evidenced by the teachings of Fath and Pineau.

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Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MICHELE FLOOD
PATENT EXAMINER
MCF

A handwritten signature in cursive script that reads "Michele C. Flood".

November 17, 2003